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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61B 17/82, 17/064

A1

(11) International Publication Number: **WO 00/64366**

(43) International Publication Date: 2 November 2000 (02.11.00)

(21) International Application Number: PCT/EP00/03743

(22) International Filing Date: 18 April 2000 (18.04.00)

(30) Priority Data:
MI99A000827 21 April 1999 (21.04.99) IT

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(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

**Published**

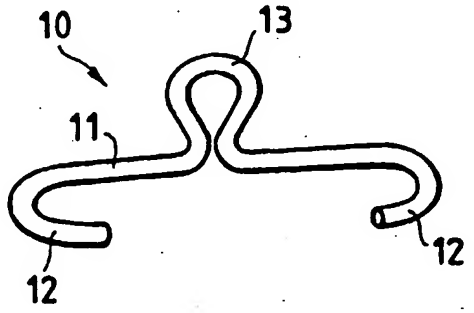
*With international search report.*

*Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.*

(54) Title: SEMI-RIGID COMPRESSIVE CLAMP FOR USE IN STERNOTOMY, AND FORCEPS FOR ITS APPLICATION

(57) Abstract

A clamp designed for use in the heart-surgery field for osteosynthesis following on sternotomy has a roughly C-shaped configuration with a core (11) terminating at opposite ends with hooks (12) set opposite to one another. In the centre, the said core (11) extends vertically according to a plane which is substantially perpendicular to the one on which the end hooks (12) lie, with a loop (13) which is elastically compliant. The said clamp is made of a so-called "shape-memory" metallic alloy, i.e., an alloy which is malleable at a low temperature and which re-acquires its original form at body temperature, exerting a semi-rigid compression on the ends or edges of the bones requiring synthesis.



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"Semi-rigid compressive clamp for use in sternotomy, and forceps for its application"

The present invention refers to a semi-rigid compressive clamp designed for use in the heart-surgery field for osteosynthesis following on sternotomy. The invention moreover refers to a forceps for the application of said clamp.

As is well known to those skilled in the sector, at present one of the systems most widely used for osteosynthesis following on sternotomy involves the use of steel wires, which are made to pass at the rear of the sternum and are tied at the front.

However, the use of steel wires gives rise to a number of serious problems as described below.

Following upon mobilization of the patient after sternotomy has been carried out, it frequently happens that the steel wires are not able to guarantee optimal osteosynthesis. This is due to the fact that muscular tension during dilation of the thoracic cage (even simply on account of respiratory movements) causes a slight diastasis of the sternal segments, which the steel wire is unable to correct since it is not elastic. There thus remains a certain laxity of the

osteosynthesis.

The looseness of grip of the steel wire, which occurs following upon mobilization, above all in patients who are at risk, may cause displacement of the closing knot. The knot itself in these cases causes decubitus of the soft tissue overlying the sternum.

Furthermore, the use of steel wires generally causes a considerable lysis of the bone on the sternal margin.

Another drawback is due to the fact that the point of tying of the steel wires at the front of the sternum may remain slightly raised with respect to the plane of the bone.

In addition, the steel wires for sternal synthesis must be removed before any instrumental investigations, such as x-rays or CAT imaging, are carried out in so far as the wires prevent visualization of the underlying structures.

The general purpose of the present invention is to overcome the above-mentioned drawbacks of the known art, which, in the field of heart surgery, for osteosynthesis following on sternotomy envisages the use of steel wires, which are made to pass behind the sternum and then are tied in front.

This purpose is achieved by the use of a semi-rigid compressive clamp having the characteristics described in the attached main claim and in the subordinate claims.

Another purpose of the invention is to make a clamp that is particularly suited to the application of the said clamp in position.

The structural and functional characteristics of the invention and its advantages with respect to the known art will emerge as clearly understandable from an examination of the following description which refers to the attached drawings showing an example of practical embodiment of the present invention. In the drawings:

- Figure 1 is a perspective view illustrating a clamp made according to the present invention;
- Figure 2 is a front elevation of the clamp of Figure 1;
- Figure 3 is a plan view of the clamp of Figures 1 and 2;
- Figure 4 is schematic view illustrating a plurality of clamps according to the invention, applied for osteosynthesis following on sternotomy, in the open condition;
- Figure 5 is a view similar to Figure 4, but

illustrating the clamps in the closed condition;

- Figure 6 is a plan view illustrating forceps for the application of the clamp of Figure 1-5, in the open condition;

- Figure 7 is a front elevation of the forceps of Figure 6, with the clamp inserted between the jaws during closing; and

- Figure 8 is a view similar to Figure 7, illustrating the forceps closed on the clamp in the condition of divarication of the loop, i.e., of application of the clamp in place.

In the drawings, an example of clamp made according to the principles of the present invention is indicated, as a whole, by 10, and may, for example, be advantageously made using the alloy known commercially by the registered trade-mark "NITINOL".

Components made of NITINOL have the characteristic of being malleable at a low temperature (from 0°C to 5°C) and of re-acquiring their initial shape at body temperature (37°C), exerting a semi-rigid compression on the ends or edges of the bones requiring synthesis.

These components are commonly called "shape memory" components. The "shape memory" effect lies in the

capacity of the alloy, when subjected to heating, to recover the plastic deformation to which it can be subjected in low-temperature conditions.

The above phenomenon occurs on account of the transformation of the crystalline structures caused by a slight, reversible, movement of flow of each individual atom (martensitic transformation).

The amount of force that is developed in the phase of recovery of shape depends upon factors determined by the constructional peculiarities of the product; namely:

- the dimensions of the implant;
- the parameters of the semifinished product from which the implant is produced; and
- the shape of the cortical spring.

As far as temperatures are concerned, implants made of NITINOL:

- are malleable at manipulation temperatures (Mf);
- start the memory action at the start temperatures (AS); and
- finally return to their original shape at finish temperatures (Af).

As may be clearly seen, the sternal clamp 10 illustrated in Figures 1-3 of the drawings has a roughly C-shaped configuration, with a core 11

terminating at opposite ends with hooks 12 set opposite to one another.

At the centre, the core 11 extends vertically according to a plane which is perpendicular to the one on which the end hooks 12 lie, with a loop 13 (cortical spring) which is elastically compliant.

Using a clamp made of NITINOL, having the configuration described above with reference to Figures 1-3 of the drawings, it is possible to position the ends 12 of the C-shaped part 11 in the intercostal spaces S, as represented schematically in Figures 4 and 5, after the loop 13 has been opened (divaricated) at a low temperature (from 0°C to 5°C).

Next, it suffices merely to irrigate all the clamps 10 (positioned as shown in Figure 4 in the open condition) with physiological solution at body temperature for each clamp 10 to re-close by re-acquiring its original shape (see Figures 1-3), so gripping the sternum firmly (Figure 5).

More precisely, the procedure of application of the clamps according to the invention is described below.

Each clamp is sterilized by putting it in a container that can undergo autoclaving.

The autoclaved container is cooled to a temperature of generally between 0°C and 5°C. It is, in fact, advisable to expand (i.e., divaricate) the clamp cooled to a temperature of lower than 5°C to achieve the dimension suitable for its insertion into position, paying particular attention not to modify the curvature of the hooks 12 of the clamp itself so as not to alter the correct anchorage for primary fixation.

The reduction of the sternal osteotomy is blocked using a "BACKHAUS" forceps.

In the intercostal spaces, access paths of adequate dimensions are created for insertion of the terminal hooks 12 of each clamp, as close as possible to the sternum, passing through the anterior and posterior intercostal ligaments.

Using a gauge, the horizontal dimensions of the sternum are identified at the level of each individual intercostal space chosen for positioning the clamp.

From among the cooled clamps available, the ones compatible with the dimensions of the sternum as previously identified are used, bearing in mind that the dimensions of the clamp must be smaller by approximately 7-8 mm.

The clamp is now introduced, orienting the cortical spring (elastic loop 13) upwards.

The clamp thus positioned resumes its original shape at body temperature, thus firmly gripping the sternum, as shown in Figure 5.

In this way, the synthesis of the sternum takes place without the latter being surrounded by steel wires - as in the known art -, so preserving the structures of the mediastinum.

The advantages of a semi-rigid compressive sternal clamp for use in sternotomy, such as the one described above with reference to Figures 1-5 of the drawings may be summarized as below.

Any laxity of the osteosynthesis, which is always present in those cases where osteosynthesis following on sternotomy is carried out using steel wires, is prevented. In fact, the problem of laxity cannot arise when NITINOL clamps according to the present invention are used, since, owing to the superelasticity of the material, these clamps always maintain their elastic compression.

Mobilization of the patient is thus facilitated and may be envisaged at an early stage without this being detrimental to synthesis of the bone, as instead occurs when steel wires are used.

In addition, the characteristic of the material is such as to cause a markedly lower degree of lysis of the bone on the sternal margin, as compared to the lysis caused by steel wires.

Furthermore, reduction of osteolysis proves extremely useful in operations on patients who are at risk because they are affected by other illnesses (osteoporosis, diabetes, etc.) in which the bone has a lower density.

The use of sternal clamps according to the present invention is particularly indicated in re-implants in the case of post-operative dehiscence - especially if this occurs late - in which isolation of the adhesions underlying the sternum, which is necessary for closing with steel wires, may jeopardize the internal mammary artery on both sides. In these cases, approximation of the sternum, without this being surrounded by steel wires, may be advisable, as well as being far more convenient.

When NITINOL clamps according to the present invention are used, considering the geometry of the product, decubitus of the soft tissue overlying the sternum, which is caused instead by displacement of the closing knot in the case where steel wires are

used, cannot arise.

In addition, the characteristics of "NITINOL" are such that this alloy does not interfere with ionizing radiation, and hence instrumental examinations (x-rays or CAT imaging) may be carried out without prior removal of the bone-synthesis clamps.

NITINOL does not present elastic fatigue, is non-toxic, and has a higher biocompatibility than do other implants made of special steel.

Finally, the sternal clamps according to the present invention may also be used in paediatric surgery. For such an application, both the dimensions and the compressive force are adapted in proportion to the smaller resistance of the bone.

Also in this case, removal of the means of synthesis is not required since, with the growth of the sternum, the clamps are englobed in the bone.

Figures 6-8 of the drawings illustrate an example of forceps which can be used for the divarication of the loop 13, which can, in this way, be applied *in situ*, as shown in figure 4.

The said forceps is indicated as a whole by the reference number 20, and consists of two levers 21, 22 pivoted together at an intermediate point 23.

Each of the said levers 21, 22 terminates, at one end, with a grip which can be of any shape, for example, it can have the shape of an arched section 24, whilst at the opposite end the levers are equipped with respective opposed jaws 25, 26.

The jaw 25 has a fret-shaped cross section identifying a C-shaped seat 27 from which opposite flanges 28 extend, the seat being designed to house the clamp 10.

More precisely, the seat 27 has a recess or "cradle" 29 for receiving the loop 13, whilst the core 11 of the clamp 10 bears upon the flanges 28, as illustrated in Figure 7.

The jaw 26 has, instead, a wedge-shaped cross section that has a groove as indicated by 29'.

Operation of the forceps according to the invention is evident from Figures 6-8 and is briefly described in what follows.

The clamp 10 is positioned between the jaws 25, 26 (which are partially closed), as shown in Figure 7.

Next, the forceps is closed completely, as shown in Figure 8, so as to cause the wedge-shaped jaw 26 to insert inside the loop 13, which is thus divaricated.

In this condition, the clamp 10 may be applied in

situ, as shown in Figure 4.

In this way, the purposes mentioned in the preamble of the description are achieved.

The scope of the present invention is defined by the ensuing claims.

CLAIMS

1. A clamp designed for use in the heart-surgery field for osteosynthesis following on sternotomy, characterized in that it has a roughly C-shaped configuration with a core (11) terminating at opposite ends with hooks (12) set opposite to one another, in the centre the said core (11) extending vertically according to a plane which is substantially perpendicular to the one on which the end hooks (12) lie, with a loop (13) which is elastically compliant, the said clamp being made of a so-called "shape-memory" metallic alloy, i.e., an alloy which is malleable at a low temperature and which re-acquires its original form at body temperature, exerting a semi-rigid compression on the ends or edges of the bones requiring synthesis.

2. A clamp according to Claim 1, characterized in that the said metallic alloy is the one commercially known by the trade-mark name "NITINOL".

3. A forceps for the application of the clamp as claimed in Claim 1, characterized in that it comprises two levers (21, 22) hinged together at an intermediate point (23), the said levers being provided with respective opposed jaws (25, 26)

between which the said clamp may be inserted, the said jaws being provided with means for divaricating the loop (13) of the clamp in the position of closing of the forceps.

4. A forceps according to Claim 3, characterized in that the said divaricating means consist of a seat for the clamp (10) in the jaw (25) and of a wedge-shaped section in the jaw (26) which is designed to wedge into the loop (13) so as to divaricate it when the forceps is closed.

5. A forceps according to Claim 4, characterized in that the said jaw (25) has a fret-shaped cross section identifying a C-shaped seat (27) from which opposite flanges (28) extend, the seat being designed to house the clamp (10) with the core (13) bearing upon the said flanges (28).

6. A forceps according to Claim 5, characterized in that the said seat (27) has a recess or "cradle" (29) for receiving the loop (13), whilst the wedge-shaped section of the jaw (26) has a groove (29').

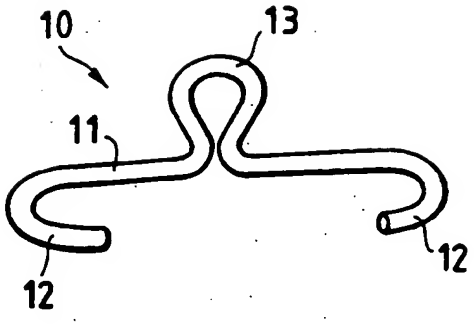



Fig.1

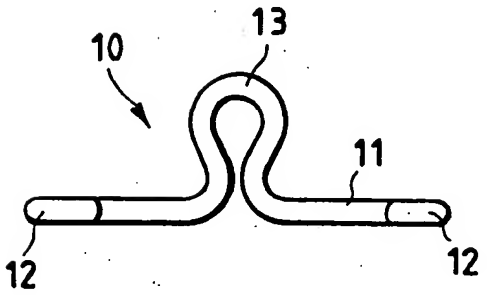



Fig.2

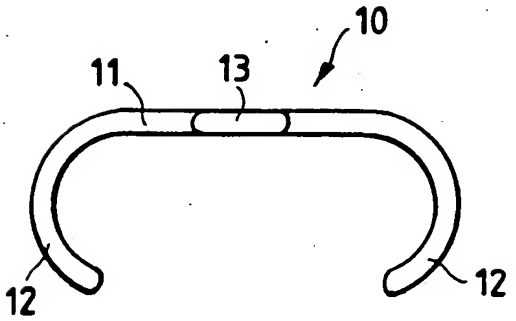



Fig.3

Fig.4

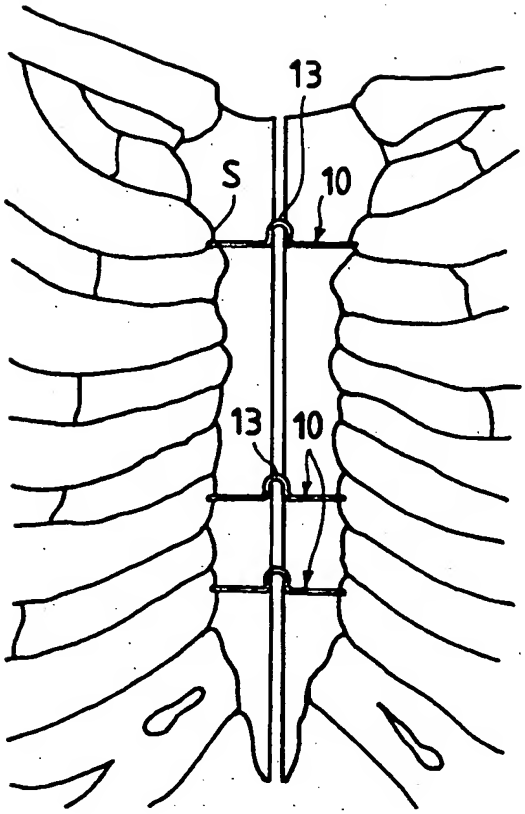



Fig.5

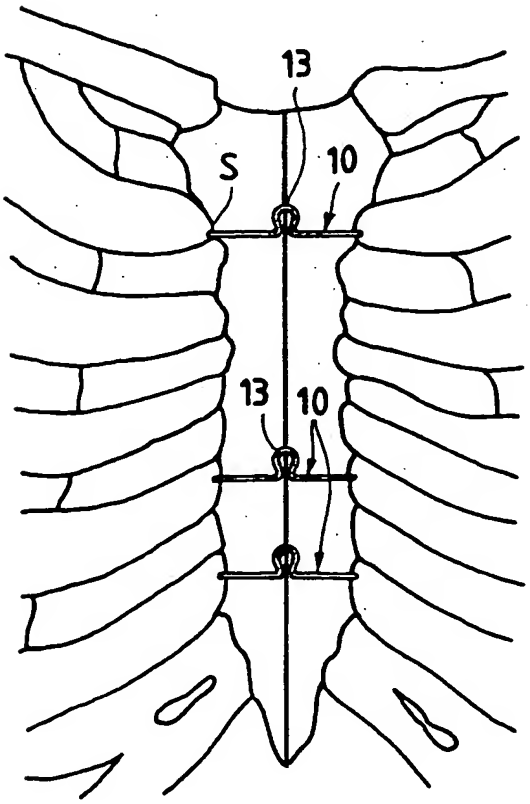
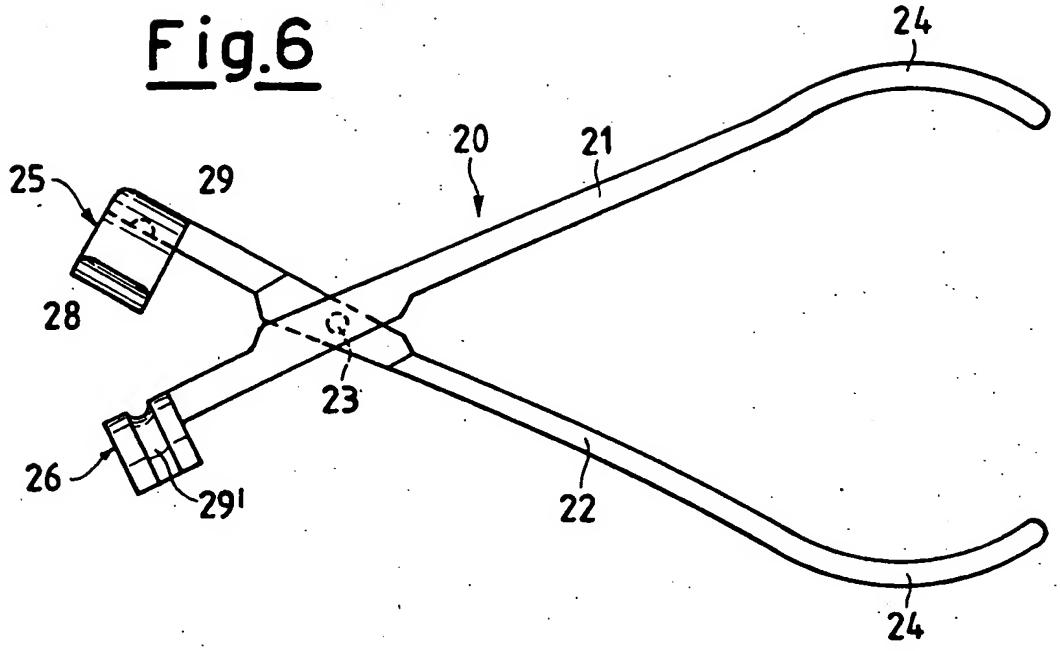


Fig.6



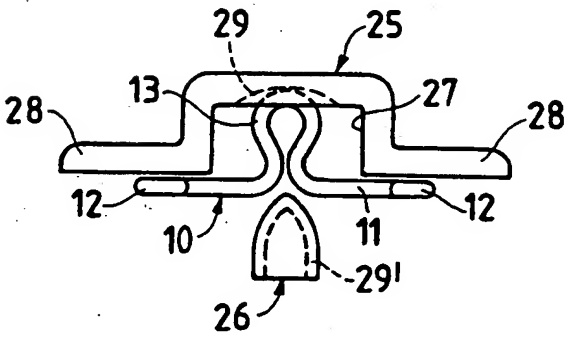




Fig.7

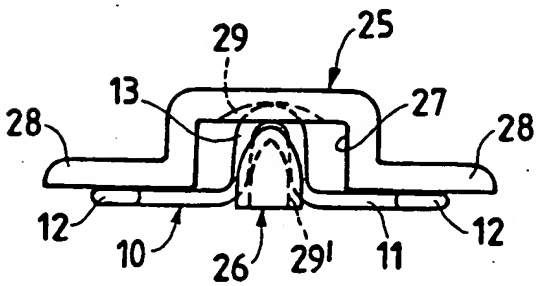



Fig.8

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A. CLASSIFICATION OF SUBJECT MATTER
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C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | EP 0 743 045 A (GAZZANI ROMOLO IGINO ;SHABOLDO OLEG PAVLOVICH (RU)) 20 November 1996 (1996-11-20) abstract column 2, line 55 -column 3, line 8 column 7, line 10 - line 12 figures 3,4 --- | 1,2 |
| Y | EP 0 386 361 A (ETHICON INC) 12 September 1990 (1990-09-12) column 4, line 48 -column 5, line 1; claim 1; figures 2A,2B,10 --- | 1-3 |
| Y | US 5 246 443 A (MAI CHRISTIAN) 21 September 1993 (1993-09-21) column 4, line 4 - line 9 column 5, line 5 - line 21 claim 1; figures 1,2 --- | 1-3 |
| | -/-- | |

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication,where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| A | DE 42 10 801 A (ROSSAR INGENEERING GBR GES FUE) 5 November 1992 (1992-11-05) page 5, line 14 - line 22; figures 6,9 | 1,2 |
| A | US 2 684 070 A (KESLEY) 20 July 1954 (1954-07-20) claim 1; figures 4,10 | 1 |
| A | US 4 217 902 A (MARCH ALFRED L) 19 August 1980 (1980-08-19) column 2, line 44 - line 54; figures 1-3 | 1,3 |
| A | FR 2 718 634 A (DYNAMIQUE SANTE SARL) 20 October 1995 (1995-10-20) the whole document | 1,2 |
| A | US 4 201 215 A (CROSSETT E S ET AL) 6 May 1980 (1980-05-06) abstract; figures 1,7,9 | 1,3 |
| A | EP 0 826 340 A (BAROUK LOUIS SAMUEL ;MEDINOV AMP (FR)) 4 March 1998 (1998-03-04) the whole document | 1,3 |

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Int tional Application No
PCT/EP 00/03743

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---|---|---|
| EP 0743045 A | 20-11-1996 | RU 2078551 C | 10-05-1997 |
| | | RU 2089124 C | 10-09-1997 |
| | | RU 2113186 C | 20-06-1998 |
| | | EP 0873718 A | 28-10-1998 |
| EP 0386361 A | 12-09-1990 | CA 2000360 A | 11-04-1990 |
| | | GR 89100652 A | 29-11-1990 |
| | | PT 91958 A | 30-04-1990 |
| US 5246443 A | 21-09-1993 | FR 2668361 A | 30-04-1992 |
| | | AU 641556 B | 23-09-1993 |
| | | AU 8676791 A | 07-05-1992 |
| | | EP 0488906 A | 03-06-1992 |
| | | NZ 240371 A | 26-08-1993 |
| DE 4210801 A | 05-11-1992 | NONE | |
| US 2684070 A | 20-07-1954 | NONE | |
| US 4217902 A | 19-08-1980 | NONE | |
| FR 2718634 A | 20-10-1995 | NONE | |
| US 4201215 A | 06-05-1980 | NONE | |
| EP 0826340 A | 04-03-1998 | FR 2752720 A | 06-03-1998 |